Application/Control Number: 10/565,126 Page 2

Art Unit: 1645

## **DETAILED ACTION**

#### Amendment

1. The amendment filed on 8/7/09 is acknowledged and entered.

### Status of claims

2. Claims 1 and 2 have been amended.

Claims 3, 10-20, 22, 24-27 and 29 are canceled.

Claims 1, 2, 4-9, 21, 23 and 28 are pending. The examiner added SEQ.ID.NO:122 to the claimed invention as the elected invention drawn to an immunogenic composition comprising two to ten antigens.

### Specification Informalities

3. In view of amendment to the specification and submission of the substitute sequence listing, the specification informalities have been withdrawn.

#### Examiner's amendment

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa M. Hemmendinger, 11/2/09 (see attached interview summary). The application has been amended as follows:

Claims 2 and 28 are canceled.

Claim 1. (Currently amended) An immunogenic composition comprising a combination of *Streptococcus pyogenes* (GAS) antigens in substantially pure form, said combination consisting of two to ten GAS antigens, wherein said combination includes <u>SEQ.ID.NO:122</u>, a Spy0269 antigen and <u>SEQ.ID.NO:1</u>, aSpy0416 antigen.

Application/Control Number: 10/565,126 Page 3

Art Unit: 1645

5. In view of amendment to the claims and arguments of record, the rejections of record under 35 U.S.C. 112 first paragraph and 35 U.S.C.102 (b) are withdrawn. Therefore, claims 1, 4-9 and 23 are found allowable.

6. Claims 1, 4-9 and 23 directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claim 21, group IV, directed to the process of using an allowable product, previously withdrawn from consideration as a result of a restriction requirement hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on , 7/21/08 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

## Reasons for allowance

Claims 1, 4-9, 21 and 23 are allowable because the prior art, Biswas et al (Infection and Immunity, 2001) does not teach or suggest an immunogenic composition comprising a combination of *Streptococcus pyogenes* (GAS) antigens in a pure form, said combination consisting of two to ten GAS antigens, wherein said combination includes SEQ.ID.NO:122, a Spy0269 (GAS40) antigen and SEQ.ID.NO:1, aSpy0416 (GAS 57) antigen. Applicant's specification teaches a method for the therapeutic or prophylactic treatment of *Streptococcus pyogenes* using GAS 40, SEQ.ID.NO:122 antigen (see Example 4).

# Conclusion

- 8. Claims 1, 4-9, 21 and 23 are allowed and are numbered as 9 respectively.
- 9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Application/Control Number: 10/565,126 Page 4

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956.

Respectfully, /Padma V Baskar/ Examiner, Art Unit 1645

/Robert B Mondesi/ Supervisory Patent Examiner, Art Unit 1645